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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/622,816

07/17/2001

Guy Weinberg

27611 35364

4693

7590

11/15/2005

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/622,816	WEINBERG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 8-18-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3-6,8,12,16,18,21,22,24,25,27-29 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6,8,12,16,18,21,22,24,25,27-29 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment dated 8-18-05 is acknowledged.

Claims included in the prosecution are 3-6, 8, 12, 16, 18, 21-22, 24-25, 27-29 and 36-39.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 3-6, 8, 12, 16, 18, 21-22, 24-25, 27-29 and 36-39 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the removal of bupivacaine by administering

Intralipid emulsions intravenously, does not reasonably provide enablement for generic emulsions and the removal of toxins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Instant claims are drawn based on a finding that bupivacaine amounts are reduced by intravenously administering a lipid emulsion containing a specific lipid, intralipid. Toxin is a generic term which virtually could include multitudes of structurally dissimilar compounds (bupivacaine is structurally different from gasoline and alcohol for example) and just because a specific lipid was able to remove some of the circulating bupivacaine, one cannot expect an emulsion containing any lipid would remove any toxin from circulation. If an oil component in an emulsion has that property, one would expect injected oil in an emulsion to remove, even compounds, which are normally present in the blood, but are not considered as toxins. Broad claims must have broad basis of support in the

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specification. In the absence of such support, claims must be limited to the removal bupivacaine by intralipid containing emulsions.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-6, 8, 12, 16, 18, 21-22, 24-25 and 27-29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from the claims whether the emulsions are oil in water or water in oil emulsions

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 3-6, 8, 12, 16, 18, 21-22, 24-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asher cited above by itself or in combination with Takami (4,323,563) and Hope (6,139,871).

Asher discloses lipid emulsions containing either mineral oil or a vegetable oil, a surfactant, 1-5 % (emulsifier), sucrose (tonicity modifier) for the removal of toxic agents (abstract, col. 3, line 47 through col. 5, line 57, Examples and claims). What is lacking in

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Asher is the administration of the emulsion intravenously to remove the toxic material in circulation. However, it would have been obvious to one of ordinary skill in the art to administer Asher's emulsions intravenously if the toxins to be removed are in circulation since Asher has shown the emulsion's ability to remove the toxins. One of ordinary skill in the art would be motivated to use Asher's emulsions intravenously, with a reasonable expectation of success, because the reference of Takami shows that fat emulsions can be injected intravenously (see abstract) and that of Hope shows that emulsions such as liposomal emulsions could be administered intravenously to remove cholesterol from blood (example 1).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the present method is directed to removing external or acute toxins from the blood stream and that are purposefully or accidentally to an individual and not directed to removing chronic or latent toxins such as cholesterol. These arguments are not persuasive. First of all, the examiner is unable to find the terms, 'acute' and 'external' toxins at these locations. As applicants themselves state, on page 4 what is stated is 'toxins that are poisonous or noxious agents present in the circulation and this does not exclude endogenous toxins. Secondly, claims are given a broadest reasonable interpretation in instant case. Applicant argues that 918 patent discloses medicinals for ingestion that may be utilized as traps for toxins present in the gastrointestinal system or as slow-release compositions for drugs and it fails to teach or suggest the use of any composition to remove toxins from the blood stream. Applicant also argues that the environments in the bloodstream and the stomach are so diverse

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that persons skilled in the art are well aware that a composition suitable for ingestion is not necessarily suitable for intravenous administration and vice versa. These arguments are not persuasive. First of all, one of ordinary skill in the art would expect a dilution effect when a composition such as an emulsion is given internally. The GI system is more hostile to a composition since it has to travel through an acidic stomach environment and prior art clearly shows that the emulsion administered orally is able to overcome this problem and remove toxic material such as ammonia. Therefore, one of ordinary skill in the art would expect at least similar effect when the composition is given intravenously for blood circulation, which is less hostile than GI environment.

Furthermore, the secondary references clearly show that emulsions can be administered intravenously and such emulsions are able to remove toxic cholesterol.

With regard to applicant's arguments that blood toxins are substantially different from toxins found in the GI system, the examiner points out that the rejected claims do not recite any specific toxin and therefore, such an argument is not a valid argument.

Furthermore, an emulsion's ability to remove a toxin depends upon the nature of the compound itself and not where it is present in the system. IN other words if an emulsion has the ability to remove a compound, then it would remove that compound whether it is present in the GI system or in blood. Applicant has not shown that to be otherwise.

Applicant's arguments that the disclosure of 563 merely teaches a specific emulsifier for preparing fat emulsions for ingestion are not persuasive since this reference is combined for its teachings of the knowledge in the art of administering emulsions intravenously. Applicant's arguments that 871 patent is directed to a composition and

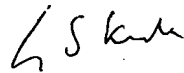
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method of removal of cholesterol and not acute toxins from the blood stream are not persuasive since as pointed out above, instant claims do not exclude toxic cholesterol.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK